

## REMARKS

The Final Office Action of January 19, 2010, has been received and reviewed. In view of the following, reconsideration is respectfully requested.

### **The Rejections under 35 U.S.C. § 103(a) are Overcome**

Claims 1-19 and 21-26 stand rejected under 35 U.S.C. 103(a) as assertedly obvious over Krone in view of Lewis and in further view of Suzuki *et al.* (U.S. 6,015,789) (hereinafter "Suzuki") and Remington's Pharmaceutical Sciences 1990 18<sup>th</sup> ed., ch. 89 (hereinafter "RPS") (collectively hereinafter "the references"). Applicants traverse the rejections.

The references cannot render obvious claims 1, 14, 24, and 26, as neither the references themselves nor the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention taught or suggested a polytartrate composition having "a lag phase of a predetermined time" in the release of a pharmaceutical composition as recited by claims 1, 24, and 26 or actually "determining a time length of the lag phase" as required by claim 14.

The Office asserts, at page 3 of the Final Office Action of January 19, 2010, that "Krone *et al.* teaches that polytartrate preparations have a decreased 'initial burst' which implies that they have a second burst." Applicants disagree. Krone, at column 1, lines 41-42, teaches that "[a]dditionally, in general after a considerable 'initial burst' only a small to moderate release rate is effected." Thus, Krone teaches that there can be an "initial burst" followed by a steady state rate without the need for any subsequent burst. Contrary to the Office's assertion, nothing in the cited references implies that an "initial burst" must be followed by a second burst. As would be understood by one of ordinary skill in the art, and as indicated by the cited section of Krone, the "initial burst" simply refers to the immediate release of the available pharmaceutical from the composition, which is then followed by a more sustained slow or moderate release rate.

In addition, Krone teaches away from compositions having a substantial "initial burst." For example, column 1, lines 37-42 of Krone teaches the disadvantages of the prior art compositions. One of these disadvantages is the "considerable 'initial burst' followed by only a small to moderate release rate." Further, Krone, at col. 2, lines 21-24, relates that the

compositions taught therein display "a strongly decreased 'initial burst' when they were used for depot preparations of pharmaceuticals." Thus, Krone teaches that the "initial burst" is unwanted and thus teaches away from the claimed compositions. Consequently, the applicants submit that the references do not teach or suggest a pulsatile release, including a lag phase, of a pharmaceutically active material.

In addition, applicants submit that the references cannot render obvious claims 2-13, 15-19, 22, 23, and 25, *inter alia*, as each of these claims depends from or otherwise incorporate all of the limitations of one of non-obvious amended claims 1, 14, and 24.

In view of at least the foregoing, applicants request withdrawal of the rejections of the claims under 35 U.S.C. § 103(a).

In light of the foregoing remarks, the applicants request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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